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2644

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,434

Applicant(s)

BERTRAM, BRIAN

Examiner

Corey P. Chau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 15, 16, 18, and 20 are objected to because of the following informalities:

Claim 15 recites "the destination" in line 2, which should be replaced with "a destination".

Claim 16, recites "the criticality" in line 2, which should be replaced with "a criticality".

Claim 18 recites "the frequency" in line 3, which should be replaced with "a frequency".

Claim 20 recites "the station" in line 2, which should be replaced with "a station" and "the detected alarm tones" in line 3, which should be replaced with "detected alarm tones". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites "amplifying the signal", which refers back to "activating a call device to transmit a signal to alert medical personnel". It is unclear to the Examiner when "amplifying the signal" occurs, before or after transmitting the signal to alert medical personnel. Claim 14 has not clearly disclose "amplifying the signal" as

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discloses in the specification on page 17, paragraph 0058 ("The transceiver 504 includes an amplifier and filter circuit (not shown). The amplifier and filter circuit are operable to amplify and filter the incoming signal 540 from the alert device 500 **prior to re-transmission to the central station**"). Appropriate corrections are require if Applicant intended to claim a signal amplified after transmitting the signal to alert medical personnel.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-3, 9-11, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Application Publication No. 20030058097 to Saltzstein et al. (hereafter as Saltzstein).

6. Regarding Claim 1, Saltzstein discloses a device to alert medical personnel (i.e. system, method and apparatus for sensing and communicating status information from a portable medical device) comprising: an audio sensor (250,209) adapted to detect an alarm state audio signal (i.e. audible alarm signal) from a medical device (101) connected to a patient (i.e. it is inherent a portable medical device such as an automated external defibrillator have electrode pads connect to the patient in order to provide shock to a patient) (page 3, paragraphs 0026-0027); and an interface adapted

to activate a medical personnel call device in response to the detection of the audio signal so that assistance can be provided to the patient (i.e. it is inherent that when an alarm signal is generated to indicate status of the portable device, such as a low battery, the control unit relays the status information received from the sensing device to a user, such as an alarm system attendant or the control unit may forward the message to another remote system, such as emergency, e.g., 911, computer aided dispatch (CAD) system, therefore providing assistance to the patient, by replacing or location another portable medical device because a nonfunctional portable medical device will not be able to help the patient) (page 2, paragraph 0021).

7. Regarding Claim 2, Saltzstein discloses the audio sensor is a microphone (209).

8. Regarding Claim 3, Saltzstein discloses the interface is a relay (page 2, paragraph 0021).

9. Regarding Claim 9, Saltzstein discloses a driver and a radio transmitter adapted to generate a unique signal and transmit the unique signal to a destination (Fig. 1; page 2, paragraph 0019).

10. Regarding Claim 10, Saltzstein discloses a radio transceiver adapted to transmit and receive signals (Fig. 1; page 2, paragraph 0019).

11. Regarding Claim 11, Saltzstein discloses a method of alerting personnel that a medical device is sounding an audible tone (i.e. system, method and apparatus for sensing and communicating status information from a portable medical device), the method comprising: detecting a medical emergency (i.e. low battery or a nonfunctional personal medical device reads on a medical emergency because it is essential for the

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portable medical device to operate properly in order to help a patient) through an audible tone generated by a medical device (250,209) (page 3, paragraph 0026); and activating a call device to transmit a signal to alert medical personnel (i.e. emergency, e.g., 911, or computer aided dispatch (CAD) system) (page 2, paragraph 0021).

12. Regarding Claim 13, as best understood with regards to the 112, 2nd problem mentioned above, Saltzstein discloses **selecting at least one** of an automatic, manual, and dual mode of operation (i.e. automatic)(page 3, paragraphs 0024, and 0026-0027).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 4, 5, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent No. 4473821 to Yang et al (hereafter as Yang).

15. Regarding Claims 4 and 5, Saltzstein discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status

signals by distinguishing different audible signals. For instance, the sensing device 250 can be configured to monitor the duration of audible signals, or the duration between audible signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status (page 3, paragraph 0026). Therefore it would have been obvious to one having ordinary skill in the art to seek known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals. Yang for example, discloses filters (46,48,50,52) (i.e. an adjustable filter adapted to select a range of frequencies of the audio signal to be detected by the audio sensor for further processing) to pass frequencies generated by the signal generators and to block all other audio frequencies received by the pick up device. The output from the filters is fed to a frequency detector (i.e. frequency counter), which detects if all frequencies are present. The frequency detector provides a signal to a variable threshold circuit to provide some alarm action (Figs. 2 and 3; column 4, lines 21-51). It would have been obvious to one having ordinary skill in the art to employ any known method to detect the presence or absence of an audible signal and/or to distinguish different audible signals, such as that of Yang. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize filters, a frequency detector, and a variable threshold circuit to pass frequencies generated by the signal generators, to block all other audio frequencies received by the pick up device and to detects if all frequencies are present, and to provide some alarm action in order to detect the presence or absence of an

audible signal and/or to distinguish different audible signals. Therefore, Saltzstein as modified discloses alarm action in order to detect the presence or absence of an audible signal and/or to distinguish different audible signals, thereby detecting audible signal indicating status such as low battery, which it is inherent to user, such as alarm system attendant, emergency, e.g., 911, or computer aided dispatch (CAD) system to provide battery or provide a functional portable medical device (i.e. determine what, is any, additional supplies are needed, and communicate with a computer to reorder needed supplies) (page 2, paragraph 0021)

16. Claim 12 is essentially similar to Claim 5 and is rejected for the reasons stated above apropos to Claim 5.

17. Claim 6 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent Application Publication No. 20040264711 to Graumann.

18. Regarding Claim 6, Saltzstein discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals. For instance, the sensing device 250 can be configured to monitor the duration of audible signals, or the duration between audible

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signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status (i.e. sample and store a plurality of audio signals generated by the medical device)(page 3, paragraph 0026). Saltzstein discloses a sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals, but only generally; no specific hardware or software is taught. Therefore it would have been obvious to one having ordinary skill in the art to seek known devices to perform the process of determining the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker or distinguishes various status signals by distinguishing different audible signals. Graumann for example, discloses signal analysis and shaping block 108 to analyzed an audio signal and possibly shape the audio signal, wherein the signal analysis and shaping block includes a digital signal processor (DSP)(i.e. microprocessor) and memory that is coupled to the DSP, wherein the DSP may be programmed to perform the signal analysis and shaping functions (page 1, paragraph 0014). It would have been obvious to one having ordinary skill in the art to employ any known devices to perform the process of determining the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker or distinguishes various status signals by distinguishing different audible

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signals, such as that of Graumann. Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein with the teaching of Graumann to utilize a digital signal processor (DSP), wherein the DSP is programmed to perform the process of determining the state of the portable medical device by detecting the presence or absence of an audible signal produced by the speaker or distinguishes various status signals by distinguishing different audible signals (i.e. microprocessor programmed to identify critical alarm audio signal, wherein the critical alarm audio signal is generated to indicate a status of the portable medical device such as a low battery signal or if a portable medical device has failed, which is essential to helping a patient).

19. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent No. 6778090 to Newham.

20. Regarding Claim 7, Saltzstein does not expressly disclose a time delay adapted to select the time delay before the interface activates the call device. Newham discloses a time delay in order to prevent improper or false activation of call device (column 7, line 42 to column 8, line 6). Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein with the teaching of Newham to utilize a time delay in order to prevent improper or false activation of call device.

21. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent No. 4539560 to Fleck et al. (hereafter as Fleck).

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22. Regarding Claim 8, Saltzstein does not expressly a remotely located reset switch adapted to reset the interface via an infrared wireless signal. However it would have been obvious to one having ordinary skill in the art to provide such a reset switch in order to reset the interface to normal operation as taught by Fleck (column 3, lines 19-26). Fleck discloses a reset circuit, which provides a continuing alarm signal until the circuit is manually reset. Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein with the teaching of Fleck to incorporate a reset switch in order for the interface (i.e. Fig. 1) to forward the status information received from the sensing device to a user, such as an alarm system attendant, any remote computer system, emergency, e.g., 911, or computer aided dispatch (CAD) system until the control unit is manually reset by the user of the portable medical device to operation in normal condition, wherein the communication between the portable medical device and the control unit may wireless telephony system, such as infrared (i.e. remotely located reset switch adapted to reset the interface via an infrared wireless signal)(Saltzstein, page 2, paragraph 0019).

23. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent Application Publication No. 20030097160 to Caby et al. (hereafter as Caby) and in further view of U.S. Patent Application Publication No. 20040172283 to Vanderveen et al. (hereafter as Vanderveen)

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24. Regarding Claim 14, as best understood with regard to 112, 2nd problem as mention above, Saltzstein discloses

a communication link between the sensing device and the control unit, wherein the communication link may be in the form of any electronic wired or wirelessly communication system, such as two-way radio, wireless telephony system, etc. (page 2, paragraph 0019), but does not expressly discloses amplify the signal. Examiner take Official Notice that it would have been obvious to amplify the signal prior to transmitting the signal to the alert medical personnel in order to drive an antenna. Saltzstein as modified discloses a portable medical device 101 may be any electronic medical device such as an automated external defibrillator (AED), but only generally; no specific hardware or software is taught. Therefore it would have been to one having ordinary skill in the art to seek known automated external defibrillator (AED). Caby for example, discloses automated external defibrillator (AED) comprising a USB hub to allow many devices to connect to the defibrillator, such as a printer, a bar code scanner, a computer keyboard, or a data transfer device for variety purposes discloses, such as using the barcode technology to support real-time verification and charting of medications being administered to a patient, as taught by Vanderveen (page 7, paragraph 0057). It would have been obvious to one having ordinary skill in the art to employ any known defibrillator, such as that of Cady and Vanderveen. Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein as modified with the teaching of Caby and Vanderveen to utilize a automated external defibrillator (AED) comprising a USB hub to allow many devices to connect to the defibrillator, such as a

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printer, a bar code scanner, a computer keyboard, or a data transfer device for variety purposes, such as using the barcode technology to support real-time verification and charting of medications being administered to a patient (i.e. using an identification system that includes a bar code for medication verification).

Saltzstein as modified does not expressly disclose transmitting alert data directly into a patient electronic medical record which can be stored in a computer database or printed to a central printer located at a central medical station. Vanderveen for example, discloses medication management and event logger and analysis system comprising a medical administration management module, wherein the medication administration management module 110 is implemented using the hardware system described above comprising a pharmacy CPU 60, barcode reader 68, and printer 66, together with a bedside CPU 80 with a connected barcode reader 90, the care management system ensures that medication is administered to the right patient, in the right dose, along the right route and at the right time. The medication administration module may also be capable of tracking specific alert conditions that are reported by specific medication administration devices indicating that particular treatment parameters have not been correctly entered into the device by a caregiver (i.e. discloses transmitting alert data directly into a patient electronic medical record). These alerts, or "events" may be either automatically stored in a database associated with the medication administration module 110, or, may be stored in a dedicated event logging/analysis and reporting server (i.e. patient electronic medical record which can be stored in a computer database). The analysis may generate reports for a specified

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medication administration device or the analysis may consolidate event reports from all, or a selected subset of, the medication administration devices in an institution, and may provide reports in accordance with either customized formats or formats pre-established by the institution (i.e. printed to a central printer located at a central medical station)(Figs. 1-3; page 8, paragraphs 0065 and 0069). Therefore it would have been obvious to one having ordinary in the art to modify Saltzstein with the teaching of Vanderveen to incorporate medication administration module which receives status information from the control unit, wherein the medication administration module is capable of tracking specific alert conditions that are reported by specific medication administration devices indicating that particular treatment parameters have not been correctly entered into the device by a caregiver (i.e. discloses transmitting alert data directly into a patient electronic medical record). These alerts, or "events" may be either automatically stored in a database associated with the medication administration module 110, or, may be stored in a dedicated event logging/analysis and reporting server (i.e. patient electronic medical record which can be stored in a computer database). The analysis may generate reports for a specified medication administration device or the analysis may consolidate event reports from all, or a selected subset of, the medication administration devices in an institution, and may provide reports in accordance with either customized formats or formats pre-established by the institution (i.e. printed to a central printer located at a central medical station)(Figs. 1-3; page 8, paragraphs 0065 and 0069). Therefore, ensures that medication is administered to the right patient, in the right dose, along the right route and at the right time.

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25. Regarding Claim 15, as best understood with regards to the 112, 2nd problem mentioned above, Saltzstein as modified discloses the signal includes identification of a patient (i.e. barcode reader is capable of identifying patient) (Vanderveen, Fig. 4; page 6, paragraph 0053), and wherein the identification is displayed at the destination to inform the personnel of the medical device that is sounding the audible tone (Vanderveen, Fig. 2).

26. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent Application Publication No. 20050085860 to Herbert.

27. Regarding Claim 16, as best understood with regards to the 112, 2nd problem mentioned above, Saltzstein discloses comparing the audible tone to a group of audible tones to determine the criticality of the audible tone (page 3, paragraph 0026), but does not expressly the audible tone relative to patient health. Saltzstein discloses although theses specific examples of status indicators are used for illustrative purposes, the scope of the present invention included the detection of any signal, generated by a portable medical device (page 2, paragraph 0020; page 3, paragraph 0023). Herbert discloses a portable defibrillator comprising a processor to communicate a status of a patient to the defibrillator user through indicators or a loudspeaker (page 2, paragraph 0020). Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein with the teaching of Herbert to have the portable medical device capable of detection of any signal such as a status of the patient generated by a

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loudspeaker on the portable medical device, thereby the status signal is detected by Saltzstein sensing device, wherein the sensing device determines the criticality of the audible tone (page 3, paragraph 0026).

28. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent Application Publication No. 20030120311 to Hansen and in further view of U.S. Patent No. 4473821 to Yang and U.S. Patent Application Publication No. 20020042632 to Iazzo et al. (hereinafter as Iazzo).

29. Regarding Claim 17, Saltzstein discloses

a system, method and apparatus for sensing and communicating status information from a portable medical device, wherein the portable medical device may be any electronic medical device such as an automated external defibrillator (AED), but only generally; no specific hardware or software is taught. Therefore it would have been obvious to one having ordinary skill in the art to seek known portable medical devices such as an automated external defibrillator (AED). Hansen for example, discloses a defibrillator comprising electrode pads, wherein the electrode pads are placed on the patient and after an operator places the electrode pads on the patient, the AED analyzes the patient's ECG to determine whether the patient is suffering from a shockable heart rhythm. If the AED 12 determines that the patient is suffering from a shockable heart rhythm, then it instructs the operator to depress the shock button 30 to deliver a shock to the patient (page 1, paragraph 0008; page 5, paragraph 0059). It

would have been obvious to one having ordinary skill in the art to employ any known portable medical device, such as an automated external defibrillator (AED), such as that of Hansen. Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein with the teaching of Hansen to utilize a defibrillator comprising electrode pads, wherein the electrode pads are placed on the patient and after an operator places the electrode pads on the patient, the AED analyzes the patient's ECG to determine whether the patient is suffering from a shockable heart rhythm. If the AED 12 determines that the patient is suffering from a shockable heart rhythm, then it instructs the operator to depress the shock button 30 to deliver a shock to the patient (i.e. a patient monitor medical device) (page 1, paragraph 0008; page 5, paragraph 0059). Therefore Saltzstein as modified discloses an audio sensor (250,209) adapted to detect an audio signal generated by a patient monitor medical device (i.e. the sensing device 250 comprises a microphone 209 for sensing audible signal generated by a speaker of the portable medical device, wherein the portable medical device analyzes the patient's ECG, which reads on a patient monitor medical device).

Saltzstein as modified discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals. For instance, the sensing device 250 can be

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configured to monitor the duration of audible signals, or the duration between audible signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status (page 3, paragraph 0026). Therefore it would have been obvious to one having ordinary skill in the art to seek known method to detect the presence or absence of an audible signal and/or to distinguish different audible signals. Yang for example, discloses filters (46,48,50,52) (i.e. an adjustable filter adapted to select a range of frequencies of the audio signal to be detected by the audio sensor for further processing) to pass frequencies generated by the signal generators and to block all other audio frequencies received by the pick up device. The output from the filters is fed to a frequency detector (i.e. frequency counter), which detects if all frequencies are present. The frequency detector provides a signal to a variable threshold circuit to provide some alarm action (Figs. 2 and 3; column 4, lines 21-51). It would have been obvious to one having ordinary skill in the art to employ any known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals, such as that of Yang. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize filters, a frequency detector, and a variable threshold circuit to pass frequencies generated by the signal generators, to block all other audio frequencies received by the pick up device and to detects if all frequencies are present, and to provide some alarm action in order to detect the presence or absence of an audible signal and/or to distinguish different audible signals.

Saltzstein discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals. For instance, the sensing device 250 can be configured to monitor the duration of audible signals, or the duration between audible signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status. Although these methods of distinguishing audible status signals are disclosed in these examples, any other method of distinguishing audible signals also fall within the scope of the present invention (page 3, paragraph 0026). Therefore it would have been obvious to one having ordinary skill in the art to seek known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals. Iazzo for example, discloses a processor to compare audio signals to stored audio patterns or signature in order to determine an event has occurred (i.e. a microprocessor adapted to compare the audio signals to stored audio signals to identify the audio signal) (page 5, paragraph 0051). It would have been obvious to one having ordinary skill in the art to employ any known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals, such as that of Iazzo. Therefore it would have been obvious to one

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having ordinary skill in the art to modify Saltzstein as modified with the teaching of laizzo to utilize a processor to compare audio signals to stored audio patterns or signature in order to determine an event has occurred (i.e. a microprocessor adapted to compare the audio signals to stored audio signals to identify the audio signal), therefore providing method to detect the presence or absence of an audible signal and/or to distinguish different audible signals.

In addition, Saltzstein as modified discloses an interface adapted (Page 2, paragraphs 0019 and 0021) to activate a call device after the frequency counter reaches a predetermined threshold, wherein the frequency counter includes an analog to digital converter (i.e. is it inherent for the frequency counter to include an analog to digital converter in order to provide a digital signal to the microprocessor).

30. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent No. 4473821 to Yang and in further view of U.S. Patent Application Publication No. 20020042632 to laizzo.

31. Regarding Claim 18, as best understood with regards to the 112, 2nd problem mentioned above, Saltzstein discloses a device to alert medical personnel comprising: a microphone (250,209) adapted to detect an audio signal generated by a medical device.

Saltzstein discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of

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the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals. For instance, the sensing device 250 can be configured to monitor the duration of audible signals, or the duration between audible signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status (page 3, paragraph 0026). Therefore it would have been obvious to one having ordinary skill in the art to seek known method to detect the presence or absence of an audible signal and/or to distinguish different audible signals. Yang for example, discloses filters (46,48,50,52) (i.e. an adjustable filter adapted to select a range of frequencies of the audio signal to be detected by the audio sensor for further processing) to pass frequencies generated by the signal generators and to block all other audio frequencies received by the pick up device. The output from the filters is fed to a frequency detector (i.e. frequency counter), which detects if all frequencies are present. The frequency detector provides a signal to a variable threshold circuit to provide some alarm action (Figs. 2 and 3; column 4, lines 21-51). It would have been obvious to one having ordinary skill in the art to employ any known method to detect the presence or absence of an audible signal and/or to distinguish different audible signals, such as that of Yang. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize filters, a frequency detector, and a variable threshold circuit to pass frequencies generated by

the signal generators, to block all other audio frequencies received by the pick up device and to detects if all frequencies are present, and to provide some alarm action in order to detect the presence or absence of an audible signal and/or to distinguish different audible signals.

Saltzstein as modified discloses a first relay (page 2, paragraph 0021) adapted to activate a call device after the frequency counter reaches a predetermined threshold.

Saltzstein as modified discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals. For instance, the sensing device 250 can be configured to monitor the duration of audible signals, or the duration between audible signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status. Although theses methods of distinguishing audible status signals are discloses in these examples, any other method of distinguishing audible signals also fall within the scope of the present invention (page 3, paragraph 0026). Therefore it would have been obvious to one having ordinary skill in the art to seek known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals.

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laizzo for example, discloses a processor to compare audio signals to stored audio patterns or signature in order to determine an event has occurred (i.e. a microprocessor adapted to compare the audio signals to stored audio signals to identify the audio signal) (page 5, paragraph 0051). It would have been obvious to one having ordinary skill in the art to employ any known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals, such as that of laizzo.

Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein as modified with the teaching of laizzo to utilize a processor to compare audio signals to stored audio patterns or signature in order to determine an event has occurred (i.e. a microprocessor adapted to compare the audio signals to stored audio signals to identify the audio signal), therefore providing method to detect the presence or absence of an audible signal and/or to distinguish different audible signals.

Saltzstein as modified discloses in addition to the configurations described above, the status sensing systems can be configured to determine the position of a portable medical device, but does not expressly disclose a second relay adapted to activate the call device to transmit information related to the audio signal. However, it would have been obvious to one having ordinary skill in the art to provide such a second relay in order for the sensing device to communicate with the control unit to provide the position of a portable medical device through a relay switch, which generate electronic signal to the control unit. Saltzstein as modified does not expressly discloses wherein the information transmitted includes at least one of: patient number; room number, and

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bed number. However it would have been obvious to one having ordinary skill in the art that the position of the portable medical device can be room number.

Therefore, Saltzstein as modified discloses a central station for receiving the information and displaying it to medical personnel (i.e. the control unit 102 itself may comprise the computer dispatch system, which is inherent that the CAD system comprises a display in order to display the address of the caller on the screen).

32. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent Application Publication No. 20040264711 to Graumann.

33. Regarding Claim 19, Saltzstein discloses a system for alerting personnel comprising:

- a call device (page 2, paragraph 0021);

- a destination in communication with the call device (page 2, paragraph 0021);

and

- an alert device including an audio sensor (250,209) adapted to detect and audio signal generated by a medical device (101), a relay in communication with the call device (page 2, paragraph 0021), a display for outputting alert device information (i.e. the control unit 102 itself may comprise the computer dispatch system, which is inherent that the CAD system comprises a display in order to display the address of the caller on the screen), and a keyboard in communication with the display for the inputting of information by medical personnel (i.e. the control unit 102 itself may comprise the

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computer dispatch system, which is inherent that the CAD system comprises a keyboard in order to enter complaint information into the computer).

Saltzstein discloses a sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals, but only generally; no specific hardware or software is taught. Therefore it would have been obvious to one having ordinary skill in the art to seek known devices to perform the process of determining the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker or distinguishes various status signals by distinguishing different audible signals.

Graumann discloses signal analysis and shaping block 108 to analyzed an audio signal and possibly shape the audio signal, wherein the signal analysis and shaping block includes a digital signal processor (DSP)(i.e. processor) and memory that is coupled to the DSP, wherein the DSP may be programmed to perform the signal analysis and shaping functions (page 1, paragraph 0014). It would have been obvious to one having ordinary skill in the art to employ any known device to perform the process of determining the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker or distinguishes various status signals by distinguishing different audible signals, such as that of Graumann. Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein with the teaching of Graumann to utilize a digital signal processor (DSP), wherein the

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DSP is programmed to perform the process of determining the state of the portable medical device by detecting the presence or absence of an audible signal produced by the speaker or distinguishes various status signals by distinguishing different audible signals, in order to communicate with the control unit to relay information to a user or remote computer system (i.e. a processor adapted to activate the relay when an audio signal is detected by the audio sensor)(page 2, paragraph 0021; page 3, paragraph 0026). Therefore, Saltzstein as modified discloses the call device transmits a signal to the destination to alert personnel of the audio signal generated by the medical device in response to activation of the relay (page 2, paragraph 0022).

34. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 20030058097 to Saltzstein in view of U.S. Patent Application Publication No. 20040264711 to Graumann and in further view of U.S. Patent Application Publication No. 20020042632 to Iaizzo.

35. Regarding Claim 20, as best understood with regards to the 112, 2nd problem mentioned above, Saltzstein as modified discloses a transceiver (page 2, paragraph 0019) adapted to communication with the station and the alert device.

Saltzstein as modified discloses the sensing device 250 also comprises a microphone 209 for receiving audible signals from the speaker 112 of the portable medical device 101. In one embodiment, the sensing device 250 and microphone 209 determine the state of the portable medical device 101 by detecting the presence or absence of an audible signal produced by the speaker 112. In other embodiments, the

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sensing device 250 can be configured to distinguish various status signals by distinguishing different audible signals. For instance, the sensing device 250 can be configured to monitor the duration of audible signals, or the duration between audible signals, produced by the speaker 112 to determine a particular status or to filter false alarms. In other illustrative examples, the sensing device 250 can distinguish different volumes, tones, waveforms, frequencies, etc., to determine a particular status. Although these methods of distinguishing audible status signals are disclosed in these examples, any other method of distinguishing audible signals also fall within the scope of the present invention (page 3, paragraph 0026). Therefore it would have been obvious to one having ordinary skill in the art to seek known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals. Iazzo for example, discloses a processor (i.e. the processor operates as a comparator) to compare audio signals to stored audio patterns or signature in order to determine an event has occurred (i.e. a comparator to compare a signal with a preprogrammed signal) (page 5, paragraph 0051). It would have been obvious to one having ordinary skill in the art to employ any known methods to detect the presence or absence of an audible signal and/or to distinguish different audible signals, such as that of Iazzo. Therefore it would have been obvious to one having ordinary skill in the art to modify Saltzstein as modified with the teaching of Iazzo to utilize a processor (i.e. the processor operates as a comparator) to compare audio signals to stored audio patterns or signature in order to determine an event has occurred (i.e. a comparator to compare

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a signal with a preprogrammed signal), therefore providing method to detect the presence or absence of an audible signal and/or to distinguish different audible signals.

Response to Arguments

36. Applicant's arguments filed 4/20/2005 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an alert device hooked up to a patient which signals medical personnel of **a patient alarm state, such as bradycardia, and asystole**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

37. With respect to Applicant's argument on page 7 stating that "Saltzstein does not disclose **an alert device hooked up to a patient which signals medical personnel of** a patient alarm state, such as bradycardia, and asystole as does the present invention", has been noted. However the Examiner respectfully disagrees. Saltzstein discloses a portable medical device 101 may be any electronic medical device such as an automated external defibrillator (AED). Well-known portable medical device such as an automated external defibrillator have electrode pads connect to the patient in order to provide shock to a patient. In addition, it is inherent that when an alarm signal is generated to indicate status of the portable device, such as a low battery, the control unit relays the status information received from the sensing device to a user, such as an

alarm system attendant or the control unit may forward the message to another remote system, such as emergency, e.g., 911, computer aided dispatch (CAD) system, therefore providing assistance to the patient, by replacing or location another portable medical device because a nonfunctional portable medical device will not be able to help the patient. See page 2, paragraph 0021.

38. With respect to Applicant's argument on page 7, stating that "Saltzstein is detecting things like weak battery signals for medical equipment stored in places like a closet. Therefore, with these added limitations (which are certainly absent from Saltzstein)", has been noted. However, the Examiner respectfully disagrees. Applicant recite "medical emergency", which is not clearly defined in the claim and can be interpret as many things such as a low battery signal because a nonfunctional portable medical device will not be able to help the patient, therefore read on "medical emergency".

39. With respect to Applicant's argument on page 7, stating that "no such modes are discloses in Saltzstein and therefore claim 13 is allowable also for at least this reason", has been noted. However, the Examiner respectfully disagrees. Applicant has not clearly defined what is selecting at least one of an automatic, manual, and dual mode of operation. Therefore Saltzstein read on automatic.

40. In response to applicant's argument on page 9, that the references fail to show certain features of applicant's invention (i.e. determine what, if any, **additional supplies are needed**, and communicate with a computer to reorder needed supplies), it is noted that the features upon which applicant relies (i.e., which is primarily used to the detect

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the presence of a human) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

41. In response to applicant's argument that "claim 8 now includes the device as claimed in claim 1, further comprising a remotely located reset switch adapted to reset the interface via an infrared wireless signal. Fleck's system is a hardwired communication link from the bed to the central call station", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

42. Applicant's arguments with respect to claims 6, 14, 15, 16, and 17-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

43. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Corey P. Chau whose telephone number is (571)272-7514. The examiner can normally be reached on Monday - Friday 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chin Vivian can be reached on (571)272-7848. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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SUPERVISORY PATENT EXAMINER
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